

### **Remarks**

Applicants have carefully reviewed the Office Action mailed on April 12, 2011. Applicants respectfully traverse (and do not concede) all objections, rejections, adverse statements, and adverse assertions made by the Examiner. Claims 1, 27, 29-33, 40-49, 61 and 62 are pending in the application, with claims 1, 27, 61 and 62 being allowed, claims 29-33 being withdrawn from consideration and claims 40-49 being rejected. With this amendment, claims 40-42 are amended. There is clear support for the claim amendment in the specification and drawings as originally filed, for instance, at the bottom three paragraphs on page 21 (paragraphs [0053-0055] of the published application), and FIG. 11. No new matter is added. Claims 1, 27, 29-33, 40-49, 61 and 62 are presented for examination.

### **Allowable Subject Matter**

Claims 1, 27, 61 and 62 are allowed.

### **Specification Objections**

The specification is objected to because it does not support an embodiment comprising “a connector disposed between the flexible disk and the hemostatic body” along with the claim limitations of claims 42 and 44-49.

Although Applicants disagree with the specification objections, Applicants assert that said objections are moot in view of the amendments to claim independent 40.

Withdrawal of the specification objections is respectfully requested.

### **Drawings Objections**

The drawings are objected to because they do not show “a connector disposed between the flexible disk and the hemostatic body” along with the claim limitations of claims 42 and 44-49.

Although Applicants disagree with the drawings objections, Applicants assert that said objections are moot in view of the amendments to claim independent 40.

Withdrawal of the drawings objections is respectfully requested.

### **Claim Rejections Under 35 U.S.C. §112**

Claims 42 and 44-49 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, has possession of the claimed invention.

While Applicants disagree with these rejections, Applicants have amended the claims to further the prosecution.

In particular, Applicants have amended claim 40 to recite:

40. (currently amended) An apparatus to promote hemostasis at a blood vessel puncture site having an inner lumen pressure and an outer lumen pressure, wherein the inner lumen pressure is greater than the outer lumen pressure, the apparatus comprising:  
a flexible disk to intravascularly seal a blood vessel puncture site, the disk being sized to circumferentially cover the blood vessel puncture site and further being sufficiently flexible to conform to and seal with the blood vessel puncture site;  
a hemostatic body to seal the blood vessel puncture site; and  
~~a connector disposed between the flexible disk and the hemostatic body,~~  
the connector coupling the flexible disk to the hemostatic body, a neck having a first side attached near a center of the flexible disk and having a second side opposite the first side attached to the hemostatic body, the connector neck  
positioned within a wall of the blood vessel puncture site.

There is clear support for the claim amendment in the specification and drawings as originally filed, for instance, at the bottom three paragraphs on page 21 (paragraphs [0053-0055] of the published application), and FIG. 11. No new matter is added.

Withdrawal of the indefiniteness rejections is respectfully requested.

### **Claim Rejections Under 35 U.S.C. §103**

Claims 40-42, 44 and 45 are rejected under 35 U.S.C. §103(a) as being unpatentable over Nash et al. in U.S. Patent No. 5,700,277 in view of Hannam et al. in U.S. Patent No. 5,649,959.

Regarding claims 40-42, 44 and 45, independent claim 40 recites:

40. (currently amended) An apparatus to promote hemostasis at a blood vessel puncture site having an inner lumen pressure and an outer lumen pressure, wherein the inner lumen pressure is greater than the outer lumen pressure, the apparatus comprising:

a flexible disk to intravascularly seal a blood vessel puncture site, the disk being sized to circumferentially cover the blood vessel puncture site and further being sufficiently flexible to conform to and seal with the blood vessel puncture site;

a hemostatic body to seal the blood vessel puncture site; and

~~a connector disposed between the flexible disk and the hemostatic body,~~  
~~the connector coupling the flexible disk to the hemostatic body, a neck having a~~  
~~first side attached near a center of the flexible disk and having a second side~~  
~~opposite the first side attached to the hemostatic body, the connector neck~~  
positioned within a wall of the blood vessel puncture site.

The Examiner appears to draw a correspondence between the anchor member (32) of Nash and the “flexible disk” recited by claim 40, between the plug (30) of Nash and the “hemostatic body” recited by claim 40, and between the filament/locking member/spacer member (34/36/78) in FIGS. 6 and 9 of Nash and the “connector” recited by claim 40 prior to amendment. While Applicants disagree with these correspondences, Applicants proceed as if such correspondences hold, and demonstrate below that the cited elements from Nash do not satisfy the limitations of claim 1.

The anchor member (32) of Nash appear to be a strip of material that “is sufficiently rigid such that once it is in position within the artery or other vessel, duct, or lumen, it is resistant to deformation to preclude it from bending to pass back through the puncture through which it was first introduced.” (column 5, lines 56-60) It appears that the anchor member (32) of Nash is not flexible.

As such, Nash does not disclose the limitations of “a flexible disk to intravascularly seal a blood vessel puncture site” and “the disk being sized to circumferentially cover the blood vessel puncture site and further being sufficiently flexible to conform to and seal with the blood vessel puncture site”, as recited by independent claim 40. (emphasis added)

The filament (34) of Nash appears to connect the plug (30) to the anchor member (32) in a pulley-like arrangement from “a remote, externally located point into a passageway in the plug” (column 6, lines 10-25). FIGS. 1-9 and 19 all show the filament (34) extending proximally beyond the plug (30). It appears that the filament (34) does not have a first end attached to the anchor member (32) and a second end opposite the first end attached to the plug (30).

The locking member (36) of Nash appears to be “a disk-like or washer-like member” (column 6, lines 35-37) with a central passageway through which the filament (34) extends. The locking member (36), shown in FIGS. 4-6, does not appear to be attached to either the anchor member (32) or the plug (30).

The spacer member (78) of Nash also appears to be “a disk-like or washer-like member” (column 9, lines 18-25), also with a central passageway through which the filament (34) extends. The spacer member (78), shown in FIGS. 7-9, does not appear to be attached to either the anchor member (32) or the plug (30).

As such, Nash does not disclose the limitation of “a neck having a first side attached near a center of the flexible disk and having a second side opposite the first side attached to the hemostatic body”, as recited by independent claim 40. (emphasis added)

The filament (34) of Nash appears to pass through the opening in the vessel wall, as shown in FIGS. 3, 6, and 9. The filament (34) does not appear to be positioned within the vessel wall.

The locking member (36) and spacer member (78) of Nash appear to be disposed only outside the vessel wall, as shown in FIGS. 6 and 9. The locking member (36) and spacer member (78) do not appear to be positioned within the vessel wall.

As such, Nash does not disclose the limitation of “the neck positioned within a wall of the blood vessel puncture site”, as recited by independent claim 40. (emphasis added)

Because Nash fails to disclose the limitations of “a flexible disk to intravascularly seal a blood vessel puncture site”, “the disk being sized to circumferentially cover the blood vessel puncture site and further being sufficiently flexible to conform to and seal with the blood vessel puncture site”, “a neck having a first side attached near a center of the flexible disk and having a second side opposite the first side attached to the hemostatic body” and “the neck positioned within a wall of the blood vessel puncture site”, as recited by independent claim 40 (emphasis added), Applicants assert that independent claim 40 is patentable over Nash.

Hannam appears to disclose an anchor member (30) that “is sufficiently flexible or pliable to conform generally to the shape of the interior of the artery to as not to injure the arterial tissue.” (column 7, lines 34-37) Hannam appears to be silent regarding the

limitations of “a neck having a first side attached near a center of the flexible disk and having a second side opposite the first side attached to the hemostatic body” and “the neck positioned within a wall of the blood vessel puncture site”, as recited by independent claim 40.

As a result, Hannam cannot remedy the deficiencies of Nash in forming an obviousness rejection of independent claim 40. Consequently, Applicants respectfully submit that claim 40 is patentable over the combination of Nash and Hannam, to the extent that such a combination is even possible. Because claims 41-42, 44 and 45 depend from claim 40, they are also patentable for the same reasons as claim 40 and because they add significant elements to distinguish them further from the art.

Claims 46-49 are rejected under 35 U.S.C. §103(a) as being unpatentable over Nash et al. in U.S. Patent No. 5,700,277 in view of Hannam et al. in U.S. Patent No. 5,649,959 and further in view of Kensey et al in U.S. Patent No. 5,531,759.

As noted above, Applicants assert that independent claim 40 is patentable over the combination of Nash and Hannam.

Kensey appears to be relied on for teaching “of thea similar resilient extension member 40 comprising a hemostatic agent (Column 13, Lines 43-49, and Column 9, Lines 25-33). The outer periphery of the resilient extension member is considered a ‘dissolvable capsule’ and the center would comprise a hemostatic material.”

Kensey cannot remedy the deficiencies of Nash and Hannam in forming an obviousness rejection of independent claim 40. Consequently, Applicants respectfully submit that claim 40 is patentable over the combination of Nash, Hannam and Kensey, to the extent that such a combination is even possible. Because claims 46-49 depend from claim 40, they are also patentable for the same reasons as claim 40 and because they add significant elements to distinguish them further from the art.

Withdrawal of the obviousness rejections is respectfully requested.

### **Conclusion**

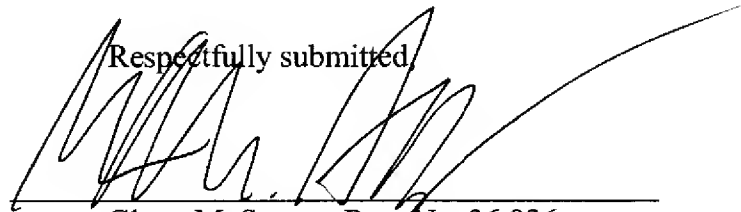
In view of the foregoing, all pending claims are believed to be in condition for allowance. Further examination, reconsideration, and withdrawal of the rejections are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If

a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

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Respectfully submitted,



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